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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,170	12/16/2005	Matti Ahlqvist	056291-5222	9593

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EXAMINER	
LAO, MARIALOUISA	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,170	AHLQVIST ET AL.	
	Examiner	Art Unit	
	M. Louisa Lao	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/16/05 10/13/ 06 6/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election of Group I (claims 1-6 and 10) in the reply filed on 6/11/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an **election without traverse** (MPEP § 818.03(a)).

2. Claims 7-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6//11/07.

3. The amended claims 2-6 and new claim 11 are acknowledged.

Provisional Obviousness Double-Patenting Rejection

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. **Claims 1-6 and 10-11 are provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-8, 10 and 14 of

copending Application No. US2005/0215630, US`630 (SN10/499042). Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutically acceptable salts of the compound of formula I of the co-pending application read on the instant salts, the instant pharmaceutical formulation comprising said salts and said formulation combined with another therapeutic agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. **Claims 1-6 and 10-11 are provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-8, 10 and 14 over claims 1-7 and 9-10 of copending Application No. US2006/0199857, US`857 (SN10/561126). Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutically acceptable salts of the compound of formula I of the co-pending application read on the instant salts, the instant pharmaceutical formulation comprising said salts and said formulation combined with another therapeutic agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Provisional Rejection Under 102(e)/103

7. Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as copending Application No. US2005/0215630, US`630 (SN10/499042) at the time this invention was made, or was subject to a joint research agreement at the time this invention was made.

8. However, reference copending Application No. US2005/0215630, US`630 (SN10/499042) additionally qualifies as prior art under another subsection of 35 U.S.C. 102, and therefore, is not disqualified as prior art under 35 U.S.C. 103(c).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 1-6 and 10-11 are provisionally rejected** under 35 U.S.C. 103(a) as being obvious over copending Application No. US2005/0215630, US`630 (SN10/499042), which has a

common assignee with the instant application. Based upon the earlier effective U.S. filing date of the copending application US2005/0215630, US`630 (SN10/499042), it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

Applicant Claims

13. The instant claims are drawn to a potassium or sodium salt of (-)-2-{[2-(4-hydroxyphenyl)ethyl]thio }-3-[4-(2- {4-[(methylsulfonyl)oxy]phenoxy} ethyl)phenyl]-propanoic acid and the pharmaceutical formulation of said salts in admixture with adjuvants; and mixture with therapeutic agents useful in the treatment of disorders, like *inter alia,* atherosclerosis.

Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)

14. US`630 teaches a compound of formula I (therein recited) and its pharmaceutically acceptable salts, prodrugs, solvates and crystalline forms thereof; the pharmaceutical formulation comprising said compound in admixture with adjuvants, combination of said compound with a therapeutic agent useful in the treatment of disorders, like *inter alia,* atherosclerosis.

Ascertainment of the Difference
Between Scope of the Prior Art and the Claims
(MPEP §2141.012)

15. US`630 differs from instant claims by its silence in the salt form, i.e., potassium or sodium, of compound of formula I.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

16. At the time of the invention, one of ordinary skill in the art looking to improve on the solubility or bioavailability of compounds of formula I would have found it *prima facie* obvious to start with the teachings of the cited prior art references. The salt forms of drugs, which render better bioavailability is a known and recognized practice (Apotex vs Pfizer March 2007). Therefore, it would have been obvious to modify the cited prior art compounds, such as by salt formation, since these are within the purview of artisan through routine experimentation, to develop a form for a more efficacious means of delivering a drug with a reasonable expectation of success.

17. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutically acceptable salts of the compound of formula I of the co-pending application read on the instant salts, the instant pharmaceutical formulation comprising said salts and said formulation combined with another therapeutic agent.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

18. No claims are allowed. The elected species of a disorder is not allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao whose telephone number is 571-272-9930. The examiner can normally be reached on Mondays to Thursdays from 8:00am to 8:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

`mll07302007
MLouisa Lao
Examiner
Art Unit 1621

for YVONNE EYLER
SUPERVISORY PATENT EXAMINER
TC1600 GAU 1621